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Application No.: 09/886,942

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4/18/2005

# AMENDMENT TO THE CLAIMS:

86 P.B 2020 0031 700

Pursuant to the proposed revisions to 37 C.F.R. § 1.121, please amend the claims as follows. The following listing of claims replaces all prior versions and listings of claims in the application:

# Listing of Claims:

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1. (Currently Amended) An isolated or recombinant nucleic acid comprising a polynucleotide sequence that has at least 99% 98% sequence identity to the entire length of the 78% polynucleotide sequence of SEQ ID NO:8 or the complementary polynucleotide sequence thereof, wherein said polynucleotide sequence promotes expression of a nucleic acid encoding a polypeptide to which the polynucleotide sequence is operably linked.

- 2. (Canceled)
- 3. (Currently Amended) The nucleic acid of claim 1 2, wherein said polynucleotide sequence promotes expression of the polypeptide-encoding nucleic acid at a level that is **about** equal to or greater than the level of expression of the polypeptide-encoding nucleic acid when the polypeptide-encoding nucleic acid is operably linked to the human CMV promoter polynucleotide sequence shown in SEQ ID NO:19 or SEQ ID NO:20.
- 4. (Previously Presented) The nucleic acid of claim 1, wherein the nucleic acid comprises the polynucleotide sequence of SEQ ID NO:8 or the complementary polynucleotide sequence thereof.
  - 5-6. (Canceled)
- 7. (Currently Amended) The nucleic acid of claim 1, comprising a polynucleotide sequence that has at least 99.5% 99% sequence identity to the polynucleotide sequence of SEQ ID NO:8 or the complementary polynucleotide sequence thereof.

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8. (Currently Amended) The nucleic acid of claim 7 1, comprising a polynucleotide sequence that has at least 99% sequence identity to the polynucleotide sequence of SEQ ID NO:8 or the complementary polynucleotide sequence thereof, wherein said polynucleotide sequence promotes expression of a polypeptide-encoding nucleic acid to which said polynucleotide sequence is operably linked at a level that is about equal to or greater than the level of expression of the polypeptide-encoding nucleic acid when the polypeptide-encoding nucleic acid is operably linked to the human CMV promoter polynucleotide sequence shown in SEQ ID NO:19 or SEQ ID NO:20.

# 9. (Canceled)

- 10. (Currently Amended) An isolated or recombinant nucleic acid comprising a subsequence of the polynucleotide sequence of SEQ ID NO:8, said subsequence comprising nucleic acid residues at positions corresponding to position 1 to about position 909 of the consensus sequence shown in SEQ ID NO:21 Figures 8A-8I, or the complementary polynucleotide sequence thereof.
- 11. (Previously Presented) The nucleic acid of claim 10, wherein the subsequence promotes the expression of a nucleic acid encoding a polypeptide to which the subsequence is operably linked.

## 12-13. (Canceled)

14. (Previously Presented) The nucleic acid of claim 1, wherein said polynucleotide sequence promotes the expression of a polypeptide-encoding nucleic acid to which said polynucleotide sequence is operably linked at a level that differs from the expression level of the polypeptide-encoding nucleic acid when the polypeptide-encoding nucleic acid is operably linked to a human CMV promoter polynucleotide sequence shown in SEQ ID NO:19 or SEQ ID NO:20.

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- 15. (Previously Presented) The nucleic acid of claim 14, wherein the polypeptide-encoding nucleic acid encodes luciferase, and the expression level is determined in an *in vitro* luciferase assay.
- 16. (Previously Presented) The nucleic acid of claim 14, wherein the polypeptide-encoding nucleic acid encodes  $\beta$ -galactosidase, the polypeptide-encoding nucleic acid is expressed in vivo, and the expression level is determined by measuring the serum titer of anti- $\beta$ -galactosidase antibodies.
- 17. (Previously Presented) The nucleic acid of claim 14, wherein the polynucleotide sequence promotes the expression of the polypeptide-encoding nucleic acid at a level that is higher than the level of expression of the polypeptide-encoding nucleic acid when the polypeptide-encoding nucleic acid is operably linked to a human CMV promoter polynucleotide sequence shown in SEQ ID NO:19 or SEQ ID NO:20.
- 18. (Previously Presented) The nucleic acid of claim 17, wherein the polynucleotide sequence promotes the expression of the polypeptide-encoding nucleic acid at a level that is 2-fold higher than the level of expression of the polypeptide-encoding nucleic acid when the polypeptide-encoding nucleic acid is operably linked to a human CMV promoter polynucleotide sequence shown in SEQ ID NO:19 or SEQ ID NO:20.

#### 19-20. (Canceled)

- 21. (Currently Amended) The nucleic acid of claim 1, wherein the nucleic acid comprises a deletion of one or more nucleotide residues in a region corresponding to **about** nucleotide residue positions 830-835 or 841-844 of the consensus sequence shown in <u>SEQ ID NO:21</u> Figures 8A-8I.
- 22. (Currently Amended) The nucleic acid of claim 21, wherein the nucleic acid comprises a deletion of nucleotide residues at positions corresponding to about nucleotide residue positions 830-835 or 841-844 of the consensus sequence.

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23. (Currently Amended) The nucleic acid of claim 22, wherein the nucleic acid comprises a deletion of the nucleotide residues at positions corresponding to about nucleotide residue positions 830-835 and 841-844 of the consensus sequence.

24-25. (Canceled)

- 26. (Currently Amended) The nucleic acid of claim 1, wherein the nucleic acid comprises an insertion of a nucleotide residue, as compared to the human Towne CMV promoter polynucleotide sequence shown in SEQ ID NO:20, after the nucleotide residue corresponding to that positioned at position 853 of the consensus sequence shown in SEQ ID NO:21 Figures 8A-8I.
- 27. (Currently Amended) An isolated or recombinant nucleic acid comprising a polynucleotide sequence having at least 99% sequence identity to a nucleotide sequence which comprises the sequence of SEQ ID NO:8 with The nucleic acid of claim 1, wherein the nucleic acid comprises a deletion of one or more nucleotide residues in a region corresponding to about nucleic acid residue positions 684-735 of the consensus sequence shown in SEQ ID NO:21 Figures 8A-8I., or to a complementary sequence thereof, wherein said polynucleotide sequence promotes expression of a nucleic acid encoding a polypeptide to which the polynucleotide sequence is operably linked.
- 28. (Currently Amended) The <u>isolated or recombinant</u> nucleic acid of claim 27, wherein the <u>isolated or recombinant</u> nucleic acid comprises a <u>polynucleotide sequence having at least 99% sequence identity to a nucleotide sequence which comprises the sequence of SEQ ID NO:8 with a deletion of nucleotide residues corresponding to <del>about</del> nucleotide residue positions 684-735 of the consensus sequence.</u>

29-30. (Canceled)

31. (Currently Amended) An isolated or recombinant The nucleic acid of claim 1, wherein the nucleic acid comprises a polynucleotide sequence comprising nucleic acid residues at

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<u>nucleic acid residue</u> positions corresponding to **about** position 1 to **about** position 930 of the consensus sequence shown in <u>SEQ ID NO:21 Figures 8A-8I</u>.

- 32. (Canceled)
- 33. (Currently Amended) The nucleic acid of claim 31 1, wherein the nucleic acid comprises a polynucleotide sequence comprising nucleic acid residues at nucleic acid residue positions corresponding to positions 1 to 932 of the consensus sequence shown in SEQ ID NO:21 Figures 8A-8I.
  - 34. (Canceled)
- polynucleotide sequence having at least 99% sequence identity to a nucleotide sequence which comprises the sequence of SEQ ID NO:8 with The nucleic acid of claim 1, wherein the nucleic acid comprises a deletion of one or more nucleotide residues in a region corresponding to about nucleotide residue positions 319-512 of the consensus sequence shown in SEQ ID NO:21, Figures 8A-8I or the complementary sequence thereof, wherein said polynucleotide sequence promotes expression of a nucleic acid encoding a polypeptide to which the polynucleotide sequence is operably linked.
- 36. (Currently Amended) The <u>isolated or recombinant</u> nucleic acid of claim 35, wherein the <u>isolated or recombinant</u> nucleic acid comprises <u>a polynucleotide sequence having at least 99% sequence identity to a nucleotide sequence which comprises the sequence of SEQ ID NO:8 with a deletion of nucleotide residues corresponding to **about** nucleotide residue positions 319-512 of the consensus sequence.</u>

37-43. (Canceled)

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44. (Currently Amended) The nucleic acid of claim 1, 10 or 12, wherein the polynucleotide sequence is operably linked to a nucleic acid encoding a polypeptide to form an expression cassette.

# 45. (Canceled)

- 46. (Currently Amended) The nucleic acid of claim 44, wherein the polypeptide-encoding nucleic acid encodes a polypeptide selected from the group consisting of a viral polypeptide, an immunogen, an immunomodulatory molecule, an antigen, an adjuvant, an allergen, an antibody, a bacterial toxin, a cytokine, a cytokine receptor, an enzyme, and a co-stimulatory molecule.
- 47. (Previously Presented) The nucleic acid of claim 46, wherein the polypeptide-encoding nucleic acid encodes an antigen selected from the group consisting of a cancer antigen, a hepatitis B surface antigen, a hepatitis A antigen, and a hepatitis C antigen.
- 48. (Previously Presented) The nucleic acid of claim 46, wherein the polypeptideencoding nucleic acid encodes a co-stimulatory polypeptide that binds to a CD28 or CTLA-4 receptor.

49-61. (Canceled)

- 62. (Currently Amended) A vector comprising at least one nucleic acid of claim 1.10, or 12.
  - 63. (Original) The vector of claim 62, wherein the vector is an expression vector.
- 64. (Original) The vector of claim 62, wherein the vector is selected from a plasmid, a cosmid, a phage, a virus or fragment thereof, a bacterial artificial chromosome (BAC), a yeast artificial chromosome (YAC).

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65. (Currently Amended) An isolated or recombinant A cell comprising the nucleic acid of claim 1 1, 10, or 12.

- 66. (Original) The cell of claim 65, wherein the cell comprises a human cell.
- 67-73. (Canceled)
- 74. (Currently Amended) A method of producing a polypeptide, the method comprising:
- (a) providing a population of cells comprising a nucleic acid of claim <u>1</u> <del>1,</del> <del>10, or 12</del> operably linked to a nucleic acid encoding a polypeptide; and
- (b) expressing the polypeptide in at least a subset of the population of cells or progeny thereof.
- 75. (Previously Presented) The method of claim 74, wherein the population of cells is provided by introducing the nucleic acid operably linked to the polypeptide-encoding nucleic acid into the population of cells.
- 76. (Original) The method of claim 74, further comprising isolating the polypeptide from the cells.
  - 77. (Original) The method of claim 74, wherein the cells are in culture.
- 78. (Original) The method of claim 77, comprising expressing the polypeptide by culturing the population or subset of the population of cells or progeny thereof in a nutrient medium under conditions in which the nucleic acid promotes expression of the polypeptide.
- 79. (Original) The method of claim 78, further comprising isolating or recovering the polypeptide from the cells or from the nutrient medium.

80-92. (Canceled)

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- 93. (Currently Amended) A kit comprising a nucleic acid of claim <u>1</u> <del>1, 10, or 12</del>.
- 94. (Previously Presented) A kit comprising a vector of claim 62.

95-105. (Canceled)

- 106. (Currently Amended) An isolated or recombinant nucleic acid comprising a polynucleotide sequence that has at least 99% 98% sequence identity to a the nucleotide sequence which comprises the sequence of SEQ ID NO:8 but lacks the nucleotide residues corresponding to the first exon, or the complementary polynucleotide sequence thereof, wherein the polynucleotide sequence promotes expression of a nucleic acid encoding a polypeptide to which the polynucleotide sequence is operably linked.
- 107. (Previously Presented) The nucleic acid of claim 1, wherein the polynucleotide sequence or complementary polynucleotide sequence thereof promotes expression of a polypeptide-encoding nucleic acid in a mammalian cell, wherein said polypeptide is capable of inducing an immune response.

#### 108-112. (Canceled)

- 113. (Currently Amended) A vector for expression of a polypeptide in a mammalian cell comprising a promoter, said promoter comprising a polynucleotide sequence having at least 99% sequence identity to the entire length of the sequence of SEQ ID NO:8, wherein said promoter is capable of directing transcription of a heterologous coding sequence operably linked downstream of the polynucleotide sequence of the promoter.
- 114. (Currently Amended) The vector of claim 113 112, wherein the polynucleotide sequence of the promoter is linked directly to the heterologous coding sequence.
- 115. (Currently Amended) The vector of claim 113 112, further comprising an origin of replication positioned upstream of and operably linked to the polynucleotide sequence of the promoter.

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116. (Currently Amended) The vector of claim 113 112, further comprising a polyadenylation region positioned downstream of and operably linked to the polynucleotide sequence of the promoter.

## 117. (Canceled)

- 118. (Currently Amended) An isolated or recombinant A cell transfected with a vector comprising the vector of claim 113 a first polynucleotide sequence having at least 99% sequence identity to the polynucleotide sequence of SEQ ID NO:8 and a second polypeptide encoding polynucleotide sequence operably linked to and positioned downstream of said first polynucleotide sequence, wherein said first polypeptide sequence is capable of directing transcription of said second polypeptide encoding polynucleotide sequence.
- 119. (Currently Amended) The <u>isolated or recombinant</u> cell of claim <u>118</u> <del>117</del>, wherein the cell is a mammalian cell.
- (New) The nucleic acid of claim 7, wherein said polynucleotide sequence promotes expression of a nucleic acid encoding a polypeptide to which the polynucleotide sequence is operably linked at a level greater than the level of expression of the polypeptide-encoding nucleic acid when the polypeptide-encoding nucleic acid is operably linked to the human CMV promoter sequence shown in SEQ ID NO:19 or SEQ ID NO:20.
  - 121. (New) A vector comprising at least one nucleic acid of claim 4.
  - 122. (New) A vector comprising at least one nucleic acid of claim 7.
- (New) The vector of claim 122, wherein said polynucleotide sequence promotes expression of a nucleic acid encoding a polypeptide to which the polynucleotide sequence is operably linked at a level greater than the level of expression of the polypeptide-encoding nucleic acid when the polypeptide-encoding nucleic acid is operably linked to the human CMV promoter sequence shown in SEQ ID NO:19 or SEQ ID NO:20.

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124. (New) The nucleic acid of claim 27, wherein the polynucleotide sequence has at least 99.5% sequence identity to a nucleotide sequence which comprises the sequence of SEQ ID NO:8 with a deletion of one or more nucleotide residues in a region corresponding to nucleic acid residue positions 684-735 of the consensus sequence shown in SEQ ID NO:21, or to a complementary sequence thereof.

- 125. (New) The nucleic acid of claim 35, wherein the polynucleotide sequence has at least 99.5% sequence identity to a nucleotide sequence which comprises the sequence of SEQ ID NO:8 with a deletion of one or more nucleotide residues in a region corresponding to nucleotide residue positions 319-512 of the consensus sequence shown in SEQ ID NO:21.
- 126. (New) The vector of claim 113, wherein said promoter comprises a polynucleotide sequence having at least 99.5% sequence identity to the entire length of the sequence of SEQ ID NO:8.

These amendments are made without prejudice and are not to be construed as abandonment of the previously claimed subject matter or agreement with any objection or rejection of record.